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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, ALEXANDER D	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,938	ROWE, PETER S.N.	
	Examiner	Art Unit	
	ALEXANDER D. KIM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 16-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/03/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Application Status

1. Claims 1-52 are pending in this instant Office action.

Election

2. Applicant's election without traverse of Group V, Claims 13-15, is acknowledged. Claims 1-52 are pending in the instant application. Claims 1-12 and 16-52 are withdrawn from consideration as non-elected inventions. Claims 13-15 will be examined herein.

Priority

3. The instant application is a 371 filing of the International Application No. PCT/US04/30530 filed on 09/20/2004, which claims benefit of US provisional application 60/504044 filed on 09/19/2003. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes both a search report and a preliminary examination report.

Examiner suggests applicants update the status of the prior filed applications in the specification's continuing data at page 1 of the specification, because the instant application is 371 of PCT/US04/30530, which claims benefit of US provisional

application 60/504044 filed on 09/19/2003. As written, instant application looks like it is claiming the benefit of US provisional application 60/504044 directly.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed on 07/03/2006 has been reviewed, and its references have been considered except where lined through.

Compliance with Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

(a) Figure 1a teaches three amino acid sequences. Labeling using a SEQ ID NO must be inserted into the brief description of the drawings or into the Figure directly. The disclosed SEQ ID NOs do not represent the full length of amino acid sequence in Figure 1a. Appropriate correction is required.

(b) Figure 8a teaches five amino acid sequences. Labeling using a SEQ ID NO must be inserted into the brief description of the drawings or into the Figure directly. Appropriate correction is required.

(c) Figure 43 teaches five amino acid sequences. Labeling using a SEQ ID NO must be inserted into the brief description of the drawings or into the Figure directly. Appropriate correction is required.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

6. The specification is objected to because of the following informalities:

(a) The specification recites "MPEP" on page 23, line 26. It should be "MEPE". Appropriate correction is required.

Claim Objections

7. Claims 13-15 are objected to because of the following informalities:

(a) Claim 13 (Claims 14-15 dependent therefrom) is objected to because of the use of abbreviation ASARM, which should be spelled out on a first appearance in claims (i.e.,

the acidic-serine-aspartate-rich-MEPE as in page 6, bottom). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13-15 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13-15 are drawn to a method of treating or inhibiting ectopic tissue mineralization in a subject comprising administering ASARM peptide to the subject such that ectopic tissue mineralization is inhibited, thereby treating or inhibiting ectopic tissue mineralization is inhibited, thereby treating or inhibiting ectopic tissue mineralization in the subject.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."

University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical Inc. v. Gen-Probe Inc.* (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from *Enzo Biochemical* (see above).

The instant specification teaches a method comprising administering ASARM peptide of SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16 for treating or inhibiting ectopic tissue mineralization in a subject. However, the breadth of claim includes a method

comprising administering a very widely varying genus ASARM peptide because the "ASARM peptide disclosed herein can also comprise any ASARM peptide fragment or variant thereof" (see page 24, lines 9-10), which encompasses a method of administering any polypeptide given broad and reasonable interpretation of "fragment" or "variant" of ASARM peptide which includes but not limited to polypeptide of SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16. Prior art by VandenBos et al. (1999, J Dent Res, Vol. 78, page 1688-1695) teach a method of administering one species, osteopontin, as described below. The specification discloses a method of administering polypeptide of SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16. Thus, prior art and the instant specification do not describe method of administering any ASARM peptide as described by the breadth of claim above for inhibiting ectopic tissue mineralization in a subject. A method of instant specification and prior arts do not describe a method of using any other species of ASARM peptide sufficiently to represent the correlation between the structure of genus ASARM and function of administering said polypeptide for treating or inhibiting ectopic tissue mineralization in a subject. Thus, the instant specification and the prior art cannot describe the structure of a very broadly claimed genus method and one skilled in the art would not be in possession of the claimed genus method by the instant specification.

9. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for a method comprising administering the ASARM peptide of SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16 for

treating or inhibiting ectopic tissue mineralization in a subject, does not reasonably provide enablement for a method comprising administering any ASARM peptide as described in the breadth of claims for treating or inhibiting ectopic tissue mineralization in a subject.

The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use of the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or

unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The nature of the invention is drawn to a method comprising administering ASARM peptide of SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16 for treating or inhibiting ectopic tissue mineralization in a subject. However, the breadth of claim includes a method comprising administering a very widely varying genus ASARM peptide because the "ASARM peptide disclosed herein can also comprise any ASARM peptide fragment or variant thereof" (see page 24, lines 9-10), which encompasses a method of administering any polypeptide given broad and reasonable interpretation of "fragment" or "variant" of ASARM peptide which includes but not limited to polypeptide of SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16. Applicants teach a method of administering an ASARM polypeptide selected from SEQ ID NO: 1, 2, 3, 4, 5, 8, 9, 13, 14, or 16 for treating or inhibiting ectopic tissue mineralization in a subject. Prior art by VandenBos et al. (1999, J Dent Res, Vol. 78, page 1688-1695) teach a method of administering one species, osteopontin, as described below. However, applicants and prior art disclose no direction or guidance on how to make and use any other ASARM peptide for the method of administering for treating or inhibiting ectopic tissue mineralization in a subject. Therefore, it is unpredictable for any ASARM polypeptide can to be administered in the method of Claims 13-15 by one skilled in the art, and one skilled in the are would not be able make and use the full scope of claims. The said unpredictability makes the relative skill required in the art very high. For all of the above

reason, it would require undue experimentation necessary for a method of administering claimed genus ASARM polypeptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by VandenBos et al. (1999, J Dent Res, Vol. 78, page 1688-1695) as evidenced by McKee et al. (1996, Microsc Res Tech, Vol. 33, pages 141-164).

Claim 13 is drawn to a method of treating or inhibiting ectopic tissue mineralization in a subject comprising administering ASARM peptide to the subject such that ectopic tissue mineralization is inhibited, thereby treating or inhibiting ectopic tissue mineralization is inhibited, thereby treating or inhibiting ectopic tissue mineralization in the subject. Claims 14-15 are drawn to a method of Claim 13, wherein the subject has ectopic mineralization associated with periodontal disease and kidney disease, respectively.

VandenBos et al. teach a method of *In vivo* administration of osteopontin (OPN) into rats (see page 1689, bottom right column), wherein the osteopontin functions "as an inhibitor of mineralization and/or mediator of cell-matricx/mineral adhesion (cohesion)

during the formation, turnover, and repair of normal and pathological mineralized tissues" (see McKee et al., top of abstract), wherein the pathological mineralized tissues includes any ectopic (i.e., abnormal) tissue mineralization. The osteopontin is encompassed by the "ASARM peptide" because it contains the ASARM-motif by the instant specification's disclosure of "ASARM-motif is found in members of the SIBLNG protein family (MEPE, DMP-1, osteopontin, DSPP)" (see page 7, line 5) and as described by the instant Figure 1B. According to MPEP §2111.02, II, "During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. It is noted that the recitation of "treating or inhibiting ectopic tissue mineralization in the subject" before the term "comprising" in Claim 13 is a preamble reciting intended use and do not contribute to a manipulative difference in recited steps of administering ASARM peptide. Claim 13 also recites "thereby treating or inhibiting ectopic tissue mineralization in the subject" at the end, which is interpreted as simply expressing the intended result of the process step and do not contribute to a positive manipulative step in the claim. Thus, a method of VandenBos et al. meets limitations of Claim 13. Claims 14 and 15 further describe "the subject". However, the subject referring in Claim 13 is recited within the description for the intended use of the claimed method and does not further limits the method step of administering in Claim 13. Thus, a method of VandenBos et al. also meets limitations of Claims 14 and 15.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656

/Kathleen Kerr Bragdon/
Supervisory Patent Examiner, Art Unit 1656